



DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO-P-2021-0052]

Grant of Interim Extension of the Term of U.S. Patent No. 7,199,162; GRAFAPEX™ (dihydroxybusulfan)

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of Interim Patent Term Extension.

SUMMARY: The United States Patent and Trademark Office has issued an order granting a one-year interim extension of the term of U.S. Patent No. 7,199,162 ('162 patent).

FOR FURTHER INFORMATION CONTACT: Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, by telephone at 571-272-7728 or by email to raul.tamayo@uspto.gov.

SUPPLEMENTARY INFORMATION: 35 U.S.C. 156 generally provides that the term of a patent may be extended for a period of up to five years, if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review. 35 U.S.C. 156(d)(5) generally provides that the term of such a patent may be extended for no more than five interim periods of up to one year each, if the approval phase of the regulatory review period is reasonably expected to extend beyond the expiration date of the patent.

On September 23, 2021, Medac Gesellschaft für Klinische Spezialpräparate mbH, the owner of record of the '162 patent, timely filed an application under 35 U.S.C. 156(d)(5) for a first interim extension of the term of the '162 patent. The '162 patent claims a method of using the human drug product known by the tradename GRAFAPEX™ (dihydroxybusulfan). The application for interim patent term extension indicates that a regulatory review period (RRP) as described in 35 U.S.C. 156(g)(1)(B)(ii) began for GRAFAPEX™ (dihydroxybusulfan) and is ongoing before the Food and Drug Administration for permission to market and use the product commercially.

Review of the interim patent term extension application indicates that, except for permission to market or use the product commercially, the '162 patent would be eligible for an extension of the patent term under 35 U.S.C. 156. Because it is apparent that the RRP will continue beyond the original expiration date of the '162 patent, i.e., October 12, 2021, interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

A first interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 7,199,162 is granted for a period of one year from the original expiration date of the '162 patent.

Robert Bahr,

Deputy Commissioner for Patents,

United States Patent and Trademark Office.

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